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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09 878,466 | 06 11 2001 | Alain Martin | | 2685 |

7590
Craig M. Bell
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05 21 2003

EXAMINER

SAUNDERS, DAVID A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1644

DATE MAILED: 05/21/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

878,466

Applicant(s)

MARTIN

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/5/02 & 2/19/03
- ☐ This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-8 is/are pending in the application.
- Of the above claim(s) 7-8 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-5 is/are rejected.
- ☒ Claim(s) 6 is/are objected to.
- ☒ Claim(s) 1-8 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The claims pending are 1-8.

Applicant's election of Group I (claims 1-6) in Paper No. 3 (filed on 11/5/02) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that, in paper no. 3, applicant argued reasons for traverse of the election of species requirement but not for the restriction of Groups requirement.

Applicant's election of urushiol, as the species of immunostimulator compound, in Paper 3 has been noted.

Applicant's election of tumor associated proteins/antigens, as the species of secondary immunostimulator compound, in Paper 3 has been noted.

Applicant's election of anthracyclines, as the species of anticancer agent, in Paper 3 has been noted.

The abstract of the disclosure is objected to because the heading "abstract of the Invention" is improper for U.S. applications. Correction is required. See MPEP § 608.01(b).

Applicant may properly recite --Abstract of the Disclosure--. MPEP 608.01(b).

Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The Markush group of claim 2 is improper by reciting only one member to select from. It is suggested that applicant recite the structural formula shown at page 6 and then recite the Markush group as the R members shown at page 7, lines 1-3.

In claim 4, line 5 "group comprising" improperly introduces the Markush group. Recitation of "--group consisting--" is suggested.

In claim 4, line 6 "and mixtures thereof" is unclear as to whether it modified only the sub-Markush group commencing at line 5 or the whole Markush Group commencing at line 2.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Boel et al. (5,877,917).

Boel et al. disclose MAGE polypeptides which serve as tumor rejection antigen precursors. Boel et al. teach use of the isolated polypeptides or the polypeptides complexed with HLA molecules as vaccines against cancer, in particular melanoma. See col. 12, line 46 - col. 13, line 2.

Claim 1 is properly anticipated because the term "immunostimulator" is taken as encompassing ^{the} vaccine disclosed by Boel et al. Note that applicant has defined immunostimulators as including "tumor associated proteins and antigens" and "tumor vaccines" (claim 3). Either of these encompass what Boel et al. teach.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Reilly et al. (WO94/23067).

Reilly et al. show peptide tumor Antigens that can associate with HLA. They teach use of such peptides in vaccines (pages 17-18); as with Boel et al., such a tumor antigen vaccine properly anticipates.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being entirely anticipated by Goodman (6,355,691).

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Goodman teaches treatment of bladder cancer with urushiol. The urushiol acts as an "immunostimulator." See col. 2, lines 35-44. Thus limitations of claims 1-3 are taught. Claim 5 is included because all that is recited after "comprising" is the administration of urushiol.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hong et al. (Arch Pharm. Res. Vol. 22, 633-64, 1999).

Hong et al. teach use of urushiol to treat cancer. They teach that such compounds have both cytotoxic activity and immunostimulating activity (page 640, col. 2); Thus the limitations of claims 1-3 are taught. Claim 5 is properly included since what is recited after "comprising" merely requires administration of Urushiol.

Claims 4 and 6 contain limitations allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 303-0196.

D. Saunders:jmr

May 14, 2003

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644